CMC

GIADENT

Intraoral Sensor

USER MANUAL

CE

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1 INTRODUCTION

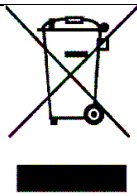
1.1 Icons used in this manual

The following icons are used in this manual:

	Indicates a "**NOTE**"; all text marked with this icon is very important and should be read carefully
	Indicates a "**WARNING**"; all text marked with this icon relate to safety issues for the patient and/or operator

1.2 Symbols used

The following symbols are used in this in this manual and on the GIADENT packaging:

Symbol	Description
	Device with Type BF applied parts
	This symbol indicates that the GIADENT sensor contains electrostatic-sensitive electronic parts susceptible to damage by electrostatic discharge. Refer to the section on Precautions for Use.
	The device contains solid materials which, at the end of its life cycle, must be disposed of at authorised recovery centres according to local regulations in order to prevent human health and environmental damages caused by improper disposal.
	NON-STERILE. GIADENT is a non-sterile product and cannot be sterilised.
	Temperature limits
	Product identification code
	Serial number

Symbol	Description
	Date of manufacture (year and month)
	Name and address of manufacturer
	Consult accompanying documents
	Conforms with EC Directive 93/42 and its amendments and supplements

1.3 General introduction

The purpose of this manual is to provide the user with the instructions necessary for safe, secure, and efficient operation of this device.

	NOTE This manual is updated to correspond to the product status it is sold with, to ensure that the user has appropriate reference on operating the device and all safety-related aspects. This manual may not reflect any product variation that has no impact on operating procedures and safe use.
	WARNING GIADENT is an electromedical device and, as such, it may only be used by dentists, radiologists or other legally qualified professionals. Proper operation requires that it be used in combination with radiographic equipment and by persons with the necessary knowledge on radiation (x-rays) protection.
	The device must be used in compliance with the procedures included in this manual and never be used for purposes other than those provided for herein.
	The user is responsible for fulfilling all legal requirements related to the installation and use of the device.
	Read this manual carefully before using the device. Keep this manual near the device for future reference.

2 GENERAL SYSTEM DESCRIPTION

GIADENT, manufactured by CMC S.r.l. is an easy-to-use digital intraoral sensor.

The system has the following unique features:

- Rounded off edges
- Smooth casing
- Outstanding cable flexibility,
- Direct connection to personal computer for image acquisition via USB direct connector.

GIADENT is based on CMOS technology, allowing the user to obtain a small pixel size (20 µm), thereby ensuring excellent spatial resolution; the use of a fiber optic plate (FOP) also helps to ensure a high quality image and, at the same time, increases the life of the sensor by protecting it against incident x-rays.

The scintillator layer can be supplied in either Cesium Iodide (CsI) or Gadolinium Oxy-Sulfide (GOS) technology.

The sensitive (active) area is available in two formats: standard size 1 and size 2 for intraoral film.

All of these features make GIADENT the perfect tool for any type of positioning, while ensuring maximum patient comfort.

GIADENT uses ARCHIMED SUITE image capturing and management software which saves images directly in DICOM format.

2.1 Intended use

The system is designed for taking intraoral x-rays of human teeth; the device can be used on all patients, regardless of their type, gender or race.

The device is designed for both the dental and radiology market. It can be installed both in dedicated facilities (hospitals or clinics) and in residential structures equipped with appropriate shielding systems.

2.2 Classification of the device in accordance with EC 93/42

GIADENT, in all of its configurations, is an active medical device, invasive through natural orifices, for temporary use, and intended for diagnostic purposes.

This device falls into Class I according to the classification directive of EC 93/42.

2.3 Applicable Standards

The standards applicable to the device mainly concern rules on general safety (for the patient and operator) and electromagnetic compatibility.

The following standards apply:

Reference standard	*Description*
CEI EN 60601-1:2005	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

2.4 Type of Installation

GIADENT is used as a temporary device and is not connected to the mains power source; power is supplied directly from the computer via the USB connection.

2.5 Address of manufacturer

The address of manufacturer is as follows:

C.M.C. S.n.c. di Cocconcelli Lauro & C.
Via Caduti delle Reggiane, 50
42122 - REGGIO EMILIA (RE) - Italy
e.mail: info@cmcreggiana.it

2.6 Physical principles of operation

The GIADENT sensor works like a regular digital sensor, i.e. it transforms the measured dose which strikes each element of the sensor (pixel) in an electric signal that can be processed through an analog-digital converter.

The conversion process includes the following steps:

1) Conversion of incident x-rays into visible light; this conversion takes place in the CsI or GOS sensitive layer.
2) The visible light is transferred, through the Optical Fibre, onto the sensitive layer of the CMOS.
3) The CMOS sensor converts the light rays into electric charges which are stored in special structures until reading

In this way, each picture element (pixel) accumulates a number of charges proportional to both the quantity of incident light beams and to the exposure time.

3 SYSTEM USABILITY

3.1 User profile and knowledge requirements

The GIADENT Medical System is designed to be used in radiography and dental facilities.

In both cases, the primary user is a professional who has the knowledge required to properly weigh the risks and benefits associated with their radiological imaging technologies.

End users must have basic knowledge about:

- Use of ionising radiation emissions
- Harmful biological effects related to excessive use of ionising radiation
- Methods to reduce the risk of excessive exposure to radiation as a patient (use of lead shields, etc.)

The operator should be familiar with using personal computers (PC) and the related programs, in order to be able to use the functions on the PC easily.

3.2 Training

After the system has been installed the operator will receive training on using the system and the image acquisition and viewing programs.

Training does not involve the use of special tools, only the digital sensor and related acquisition program.

3.3 Patient profile

The machine is suitable for use on any type of patient.
The different procedures for carrying out each exam based on the type of patient depend on the x-ray system used and are not included in this user manual.

3.4 Usability

All documentation supplied with the GIADENT system has been designed to help the operator in performing the operations.
The information contained in this manual call upon the knowledge requirements described for the user profile.

Information on using the acquisition, storage and processing system for images captured using the GIADENT sensor is available in a specific manual, which should be read for further details.

	Read this manual carefully before using the device. Keep this manual near the device for future reference.

4 SAFETY ASPECTS

	WARNING This chapter contains very important information concerning system, operator and patient safety. Read this chapter very carefully.

CMC S.r.l. designs and manufactures these devices in compliance with all relevant safety requirements. It also provides all necessary information for appropriate use and warnings on the risks associated with using X-rays for diagnostic purposes.

CMC S.r.l. shall not be held liable for:

1. use of the GIADENT device for any purpose other those for which it has been designed,

2. damage to the device, injuries to the operator or patient caused by either incorrect installation or maintenance that does not follow the procedures contained in the User and Service Manuals provided with the device, as well as incorrect operating techniques,

3. mechanical and/or electrical changes, made during or after installation, that differ from than those listed in the Service Manual,

4. only personnel authorised by CMC S.r.l. may install and perform technical work on the device.

4.1 General warnings

	WARNING GIADENT must be used in radiography, dental or hospital facilities.
	WARNING: **GIADENT and its accessories are supplied non-sterile and cannot be heat sterilized.** **Follow the instructions below to ensure proper protection of the patient and operator.**
	WARNING: Do not sterilize the GIADENT sensor in an autoclave or using dry heat as this could cause serious damage to the sensor. Do not sterilize with UV units.

	WARNING: Do not immerse the USB connector of the sensor in cleaning fluids.
	WARNING: For GIADENT to work properly, it must be connected to a personal computer designed for image acquisition and image processing. The dedicated software must be installed on the personal computer.

4.1.1 Disposal hazards

Some parts of this device contain solid materials which, at the end of its life cycle, must be disposed of at authorised recovery centres according to local regulations.

Specifically, the device contains the following materials and/or components:

- Plastic, lead, electronic boards, electronic components.

4.1.1.1 Information on proper disposal of the system or parts thereof

Applicable in the European Union and in other European countries with separate waste collection systems

In accordance with Article 13 of Legislative Decree no. 151 of 25 July 2005 "Implementation of Directives 2002/95/EC, 2002/96/EC and 2003/108/EC, on reducing the use of hazardous substances in electrical and electronic equipment, and on the disposal of waste"

	The crossed-out wheeled bin symbol on the device and/or its packaging indicates that • it was put on the market after 13 August 2005, it complies with European Directives on the disposal of electrical and electronic equipment; at the end of its useful life, the product must be collected separately from other waste and must not be handled as domestic waste but disposed of separately and delivered to an appropriate collection point for recycling electrical and electronic equipment. .scrap it according to local waste disposal regulations
Separate collection of this device when it reaches the end of its life is organised and managed by the manufacturer. The user should contact the manufacturer or its representative when it is time to dispose of the device and follow the system adopted by the manufacturer for the separate collection of end of life equipment.	

5 CLEANING AND DISINFECTING

Scrupulously following the procedures provided below in order to ensure thorough cleaning and hygiene.

	WARNING Cleaning operations must be performed with the device disconnected from the computer.
	WARNING: **GIADENT and its accessories are supplied non-sterile and cannot be heat sterilized.** **To protect the health and safety of patients and prevent possible risks of contamination and/or cross-infection, please read and carefully follow the general guidelines provide below.**

	Before each use, it is essential that you apply a protective device on the sensor. This protective device usually consists of a disposable sheath to be slipped on the sensor before use.
	Use a new protective sheath for each patient. For optimum performance, use protective sheaths specifically designed for the size of your sensor.
	Do not remove the disposable sheath by pulling on the sensor cable. Remove the protective sheath by carefully cutting it or using the tear-off strip (if provided on the sheath).
	The sensor, cable (sensor side only), and any accessories used must be carefully disinfected before each use.

5.1 Disinfection procedures

There are two levels of disinfection provided for the GIADENT sensor. Disinfect the sensor using one of the two procedures described below depending on the conditions observed.

5.1.1 First level disinfection

This disinfection procedure must be carried out the first time the sensor is used and any time the protective sheath shows signs of damage.

- Remove the protective sheath from the sensor and accessories and make sure that there are no residues of blood, saliva, tissue or secretions on it.
- Carefully check the sensor and accessories used to make sure that there are no traces of organic matter on them.
- Prepare the disinfecting solution according to the manufacturer's instructions.

- Carefully disinfect the sensor, following the instruction provided by the manufacturer of the disinfectant.

5.1.2 Second level disinfection

This procedure is required when one or more of the following issues are noted during a visual inspection:

1. the protective sheath is torn
2. residues of organic matter (blood, salvia, other types of secretions, residual tissues) are found on the sensor and/or on the sensor-PC cable connection.

If any of these issues appear, follow the steps below for the second level disinfection procedure:

- Wash the sensor thoroughly with soap and water to remove all organic matter. Be careful not to immerse the end part of the cable with the USB connection.
- Prepare the disinfecting solution according to the manufacturer's instructions.
- Carefully disinfect the sensor, following the instruction provided by the manufacturer of the disinfectant.

5.1 Disinfection products compatible with GIADENT

Use 70% isopropyl alcohol to properly clean and disinfect the GIADENT sensor.

Test carried out by the manufacture have shown that the GIADENT sensor can be immersed in the disinfection solution mentioned above without suffering any damage.

	WARNING Do not use disinfection products containing aldehydes.
	NOTE CMC Dental recommends that you only use disinfectants that are in compliance with EC Directive 93/42 on Medical Devices and that they bear the CE marking.

6 IDENTIFICATION AND DESCRIPTION

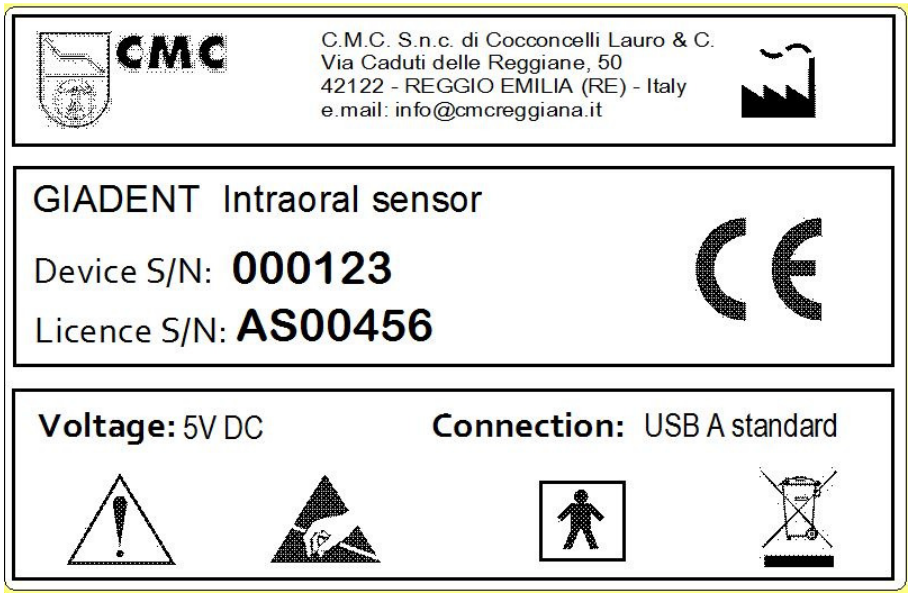
GIADENT is a device designed for taking intraoral x-rays of the human tooth structure.
Normal use and operation of this device does not involve:

- the administration of biological substances
- the sterilisation of parts of the product, since only regular cleaning is required
- the interpretation of the final results
- the updating and modification of the control software.

6.1 Nameplates

Nameplates cannot be applied to the sensor due to its size and also due to hygienic reasons.

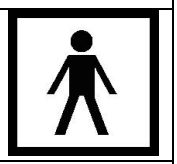
The sensor is sold in a package that shows all the data necessary for its correct identification, as shown in the image below.



Additionally, a nameplate is applied near the USB connector and bears the serial number of the sensor.

7 TECHNICAL SPECIFICATIONS

7.1 General characteristics

Characteristic	Value
Type of device	GIADENT
Manufacturer	CMC Srl
Class (according to IEC 60601-1 classification)	Class I with Type BF applied parts 
Degree of Protection	Equivalent to IP67
Sensitive (active) surface	30 x 20 mm (size 1) 33 x 25 mm (size 2)
Pixel size	20 x 20 µm
Pixel shape	Square
Number of Pixels	1500 x 1000 (size 1) 1650 x 1250 (size 2)
Distance between pixels	20 µm
Spatial resolution	20 lp/mm typical (theoretical 25 lp/mm)
Dynamic range	58 dB
Scintillator type:	CsI or GOS
Photodiode detectors	Positioned outside of sensitive area
Maximum absorb. dose	50 Gy

7.2 Mechanical characteristics

Characteristic	Value
Mechanical dimensions	25 x 39 x 12.5 mm (size 1) (L x W x H)
USB cable length	2 m

7.3 Electrical characteristics

Characteristic	Value
Supply voltage	5 V DC
Power Supply	Directly via USB connection
Maximum absorbed current	275 mA
Frame rate	0.7 fps

7.4 Electrical and optical charactyeristic

Characteristic	Value
Corrente di buio tipica @23°C	350 LSB/s
Livello di saturazione pixel (@70 kV)	340 µGy
Range dinamico	57 dB
Sensitività	15 LSM/µGy
X-RAY response nonuniformity (XRNU)	± 30 %
Total dose irradiation	50 Gy

7.5 Environmental characteristics

Characteristic	Value
Operating temperature	0 ÷ 35°C
Storage temperature	-20 ÷ +70°C
Sensor protection rating	Equivalent to IP67
Storage humidity	less than 75% non-condensing
Operating humidity	

7.6 Connection characteristics

The GIADENT sensor connects directly to the type A USB port of the computer.

The sensor is compatible with the standard USB 2 and the system is able to recognise up to three different sensors connected at the same time to the PC.

7.7 Computer specifications

The minimum system requirements for the computer used to acquire and store images are provided below.

Component	Requirements
Operating System	Windows XP® SP3, Windows Vista (32/64 bit) SP2, Windows 7 (32/64 bit) SP1, Windows 8
CPU	Intel
RAM Memory	1 GB (ideally 2 GB)
Hard drive	10 GB RAM
USB Port	2.0
Available space on HD	80 GB
Video card	1024x768 resolution in 65,000 colours (ideally 1280x1024 - 16 million colours, 32 bit)

The size of the hard drive must be proportionate to the size of the archive that is created, with particular reference to the images that will be stored it in.

7.8 Monitor specifications

A good quality monitor is essential for a correct diagnosis of the exam by analysing the image. A monitor that does not pass the required tests should not be considered a diagnostic-grade monitor. Using a non-diagnostic monitor will render the GIADENT product non-diagnostic.
A high contrast and high definition monitor that has at least a 17" screen is preferable.
Check the quality of the monitor using specific images (see paragraph 10.2)

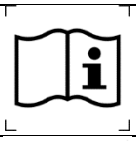
7.9 Hardware Installation

After installation, the system must not pose any risk to the patient or the operator.

Therefore, please follow the safety instructions provided below.

	The computer where our imaging systems are installed, along with all equipment connected to it, must bear the CE marking (IEC 950)
	The computer and all other associated equipment must be placed outside of the patient environment (about 1.5 m away from the chair).
	Only the sensor and x-ray generator are allowed to be placed in the so-called patient environment when using the sensor.
	Do not plug the PC used for the GIADENT sensor in a power strip.
	No additional ground receptacle is required because GIADENT is in compliance with safety standard EN 60601-1 for applied parts classified as type BF.

8 PRECAUTIONS FOR USING THE SENSOR

	For correct use of the sensor, consult the user manual.
	Use a disposable protective device (not supplied) to prevent patients from exposure to infections. Failure to use a disposable protective device may cause serious danger to the health of the patient.
	Do not sterilize the product using dry heat or autoclaving or UV devices.
	Before using the sensor, make sure it is in good condition (no cracks in the protective part of the sensor, cord ripped, etc..).
	Clean the sensor and the cable (at the output of the sensor) with a cloth moistened with 70% isopropyl alcohol for disinfection. Do not use other liquids or disinfectants and do not use too much rubbing.
	The GIADENT sensor has some electro-static sensitive parts: make sure to observe the precautions for use. Do not touch the sensor and computer screen at the same time. Do not touch the USB connector.
	When the sensor is not in use, store it away from static electricity.
	In case of any problems, do not use the product. In case of any fault during use, discontinue use of the sensor
	Do not use USB connectors/ports if they are dusty or damp.
	Handle this product with care. If the sensor is not connected to PC, be careful not to damage the USB connector.
	Do not use a wet cloth or spray on the USB connector because it will deteriorate with moisture and can cause harm to the patient and / or operator.
	Do not attach or hang anything on the sensor, especially on the sensitive part.

	Do not exert pressure on the head of the sensor (tight sensor holders, clamps, etc.)
	Do not forcibly twist, bend, pull or pinch the cable Do not pull the cable to remove the disposable protective sheath.
	When connecting/disconnecting the sensor, grasp the connector itself—never pull on the cable.
	The temperature of the sensor will rise considerably (even by 10°C) if it remains in operation for an extended period of time. Take care to use it only when the temperature is below 35° C.
	Although the sensor has been designed and engineered to be resistant to the entrance of liquids and powders, do not let the sensor immersed in liquid disinfectant, water or other chemicals for a long time.

9 SOFTWARE INSTALLATION

The GIADENT sensor comes with ARCHIMED SUITE, an image acquisition and management software program specially designed for GIADENT. ARCHIMED SUITE software is supplied on a CD/DVD ROM.
The installation process for this system entails:

1) Installation of main program
2) Installation of the protection key drivers
3) Installation of sensor drivers

Insert the CD/DVD in the CD drive of the computer where the program is to be installed; wait a few seconds until the start-up window shown below automatically appears.

☞	In the main screen of the start-up procedure, it is possible to select the language that will be used during the installation. Please select your preferred language.

9.1 Installation of program

Select button "1" to install the ARCHIMED SUITE program on your computer; the installation procedure involves a number of different steps, all of which are noted via special windows or messages.
Press the "Next" button in each window to confirm the task to perform.

☞	**NOTE** During installation you will be asked if you would like to create a desktop shortcut (to add a program icon on your desktop). We recommend that you confirm the creation of this desktop shortcut for easy access to the ARCHIMED SUITE program.

When the program is loading a progress bar will appear showing the percentage of completion of installation; when installation is completed, a window will appear confirming that the installation is complete; in this window you must select "End" to return to the main installation screen.

9.2 Installation of the protection key drivers

The ARCHIMED SUITE program is protected by a hardware protection key; without this key, the program will not work will or remain in demo mode and it will not be possible to capture images.
Install the drivers for the protection key by pressing button "2"; the installation procedure is similar to that of the main program.

9.3 Installation of sensor drivers

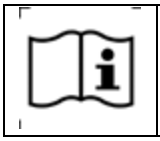
The sensor requires a special program (driver) for it to work properly; follow the following procedure:
1. Open the install disk with the command explores
2. Navigate to the folder I-View_H
3. Double click on the file "Driver Setup_32bit.exe" or "Driver Setup_64bit.exe" depending on the type of PC available.
4. Follow the step by step procedure to install the drivers.
After pressing the button, a window will appear to select the type of sensor to install: I-View D or I-View H. Select “I-View H”.

9.4 End of installation process

At the end of the installation process press the button "4" to exit the program and return to the main screen of the operating system in use.

9.5 Using the ARCHIMED SUITE program

Instructions for using the ARCHIMED SUITE are available on the software CD/DVD.
The instructions are provided in PDF format and can be accessed using Adobe Reader. If this software is not installed on your computer, you can download it for free at http://get.adobe.com/it/reader/ .

	**Read the documentation on using the ARCHIMED SUITE software carefully before you start to use it.**

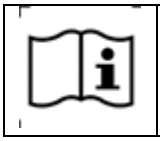
10 INSTALLATION AND PERIODIC CHECKS

After installing the GIADENT intraoral sensor, perform the following steps to ensure that everything is correctly installed and that the sensor functions properly.

1) Installation check
2) Monitor quality test
3) Spatial resolution test

10.1 Installation check

This check is performed by launching the ARCHIMED SUITE software and verifying that it works properly and recognizes the GIADENT sensor when it is connected to the computer.

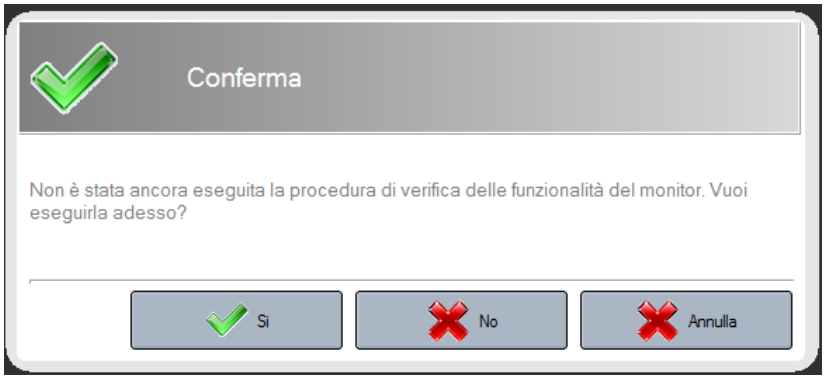
	**Read the documentation on using the ARCHIMED SUITE program carefully before you start to use it.**

	NOTE The selection of the language to be used by ARCHIMED SUITE is possible in the program's main screen and selecting "Utilities". In the new window, you can choose the desired language.

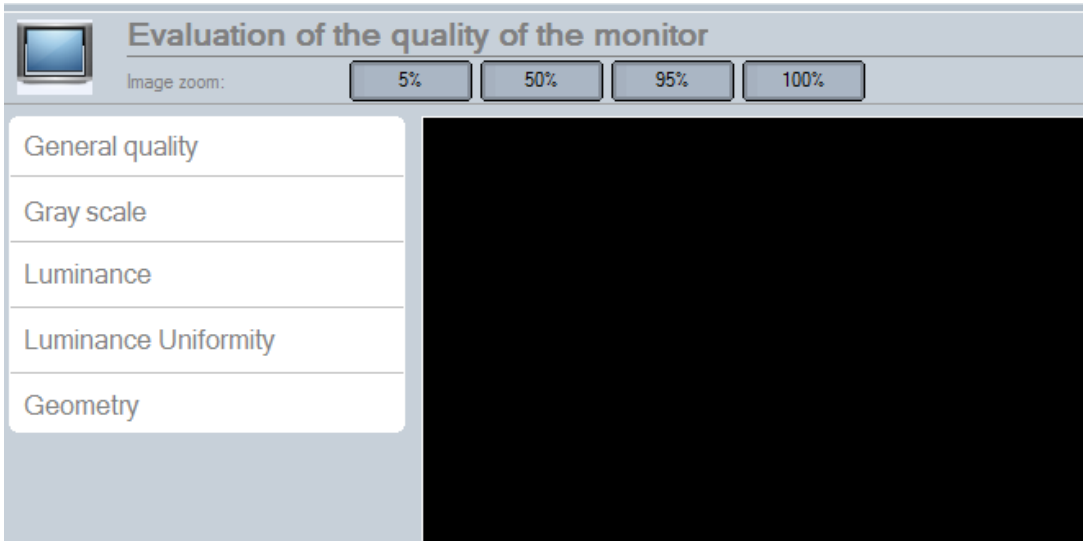
10.2 Monitor quality test

	A good quality monitor is essential for a correct diagnosis of the exam by analysing the image. A monitor that does not pass the required checks should not be considered diagnostic. Using a non-diagnostic quality monitor will render the GIADENT product non-diagnostic.

The ARCHIMED SUITE program has a guided procedure to test the quality of the monitor used. We strongly recommend that you perform the functional test for the monitor to make sure that it is suitable for viewing radiographic images. This procedure is automatically launched the first time you start the images module, as shown in the following window


Conferma
Non è stata ancora eseguita la procedura di verifica delle funzionalità del monitor. Vuoi eseguirla adesso?
Si
No
Annulla

This is a guided procedure. After confirmation the following screen will appear which includes descriptions of the tasks to perform.



Each task is associated to an appropriate image, accompanied by the related operating instructions.

Before continuing, the following general conditions must be met:

- monitors, especially CRT monitors, must be turned on for at least 30 minutes;
- no light sources are reflected on the screen;
- monitor surface is clean.

10.2.1 Frequency of monitor quality tests

We highly recommend that you perform the monitor quality test:

1) the first time using the program
2) Once every six months
3) Any time the monitor is replaced

10.3 Spatial resolution test

A spatial resolution phantom is required to perform this test. The captured images must not be adjusted in contrast or brightness.

1. Launch the ARCHIMED SUITE program to select images and create a new patient (e.g. "Periodic Check").
2. Place the phantom, with an additional filter made of 6 mm aluminium, touching the sensor, so as to cover all of the sensitive area. The sensor and phantom must be in contact with the collimator, so that they are in the centre of the beam.
3. On the x-ray generator, select the lowest exposure time possible.
4. If necessary, enable the sensor and then take the exposure

5. Check that the image obtained is properly exposed; if it is not, adjust the exposure time and repeat acquisition. In case of overexposure, increase the distance between the sensor/phantom and collimator
6. Repeat the correct exposure test; if necessary repeat steps 4 and 5 above.
7. Once a correct image is obtained you should cancel the previous images
8. Zoom in on the image and check that the line pairs are clearly visible. If necessary, adjust the contrast and brightness for optimal viewing.
9. Note the parameters used for exposure (date of execution, exposure time, focus-sensor distance, any additional filters and their characteristics, spatial resolution detected) of the image.

The test is considered passed if the spatial resolution is greater than 10 lp/mm[1].

	This test must be carried out on all x-ray generators that use the digital sensor, identifying the images for each sensor.
	If two or more digital sensors are used, the test must be carried out on each digital sensor, identifying the images for each sensor.

10.3.1 Frequency of spatial resolution test

The spatial resolution test must be performed once every 6 months.

To do so, follow the procedure described in the paragraph above; the following items must be taken into consideration during the periodic tests:

1. The results must be the same as those described for the initial system check.
2. If the visual performance appears to be degraded:
    a. perform the monitor test, checking that it corresponds to the initial quality
    b. if the results of the monitor test are positive, call the Technical Service Centre so they can check the performance of the sensor and/or x-ray generator.

10.4 Low contrast resolution test

The phantom used to test low contrast resolution also generates the image necessary to check low-resolution contrast.

Use the same procedure described above, noting also the minimum value of the step when you are able to distinguish it from the background.

[1] Standard IEC 61223-3-4 Evaluation and routine testing in medical imaging departments – Part 3-4: Acceptance tests –Imaging performance of dental X-ray equipment, a minimum value of 8 lp/mm is required for the spatial resolution acceptance and constancy test.
The sensor GIADENT has an intrinsic spatial resolution higher than stated, but the value obtained depends also on the X-ray generator used.

The test is passed if you are able to distinguish the step from 1.5 mm

10.4.1 Frequency of low contrast resolution test

This test must be performed with the same frequency as the spatial resolution test; the results must be the same as those of the acceptance test.

	If the periodic low contrast resolution test is not passed, the same considerations for the spatial resolution test apply.

10.5 Periodic maintenance

The sensor GIADENT does not require special maintenance except for of the above controls.

It is recommended, however, perform the following checks on a monthly basis:

1. Check for presence and legibility of the S/N on the plate located near the USB connector; if it appears damaged or not readable, request a copy from the manufacturer.
2. Check the integrity of the USB cable and the connector.